K050231

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
(317) 521-3544

Contact Person: Kay A. Taylor

Device Name

Proprietary name: Elecsys CA 19-9 Immunoassay
Elecsys CA 19-9 CalSet

Common name: Immunological test for CA 19-9 antigen
Calibrator

Classification name: System, Test, Carbohydrate Antigen (CA 19-9), for monitoring and management of Pancreatic Cancer
Calibrator, secondary

Device Description

The Elecsys CA 19-9 Assay is a two step sandwich immunoassay with streptavidin microparticles and electrochemiluminescence detection. Results are determined using a calibration curve that is generated specifically on each instrument by a 2 point calibration and a master curve provided with the reagent bar code.

510(k) Summary, Continued

Intended use

Immunoassay for the in vitro quantitative determination of CA 19-9 tumor associated antigen, in human serum and plasma. The assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in the monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. The electrochemiluminescence immunoassay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay systems.

Elecsys CA 19-9 CalSet is used for calibrating the quantitative Elecsys CA 19-9 assay on the Elecsys immunoassay systems.

Substantial equivalence

The Elecsys CA 19-9 immunoassay test system is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Fujirebio Diagnostics CA 19-9 RIA cleared under K020566. Both products are intended for use in the quantitative determination of CA 19-9 tumor associated antigen in human serum and plasma.

Substantial equivalence - comparison

The following table compares the Roche Elecsys CA 19-9 Immunoassay with the predicate device.

Feature	Elecsys CA 19-9	Fujirebio CA 19-9 RIA (predicate)
Intended Use	In vitro quantitative determination of CA 19-9 tumor-associated antigen in serum and plasma.	In vitro quantitative determination of CA 19-9 tumor-associated antigen in serum and plasma.
Indication for Use	An aid in the management of patients with cancers of the exocrine pancreas.	An aid in the management of patients with cancers of the exocrine pancreas.
Assay Principle	Electrochemiluminescent immunoassay	Radioimmunoassay
Sample Type	Human serum and plasma	Human serum and plasma

510(k) Summary, Continued

Feature	Elecsys CA 19-9	Fujirebio CA 19-9 RIA (predicate)
Calibrator	Elecsys CA 19-9 CalSet (2 levels)	CA 19-9 Standard set (6 levels including 0)
Controls	PreciControl Tumor Marker (2 level)	Defibrinated human plasma containing 2 levels of Ca 19-9
Instrument	Elecsys 1010, 2010 and MODULAR ANALYTICS E170	Manual method or semi-automated with commercially available rinsing/aspiration systems
Measuring range	0.60 – 1000 U/mL	0.9 – 240 U/mL

Substantial equivalence – performance characteristics

The performance characteristics of the Elecsys CA 19-9 Immunoassay and the predicate device are compared in the table below.

Feature	Elecsys CA 19-9	Fujirebio CA 19-9 RIA (predicate)
Precision	1010/2010 Within-run 2.9%-4.8% CV @ 11.1-185.4 U/mL Total Precision 2.9%-4.4% CV @ 11.1-185.4 U/mL E170 Within-run 1.2%-2.5% CV @ 5.2-379 U/mL Total Precision 1.9%-8.0% CV @ 5.57-371 U/mL	Average variability ranged from 6.7% (44 U/mL) to 15.4% (8 U/mL).
Analytical sensitivity (LDL)	0.60 U/mL	0.9 U/mL
Hook Effect	No high dose hook effect up to 500,000 U/mL	None up to 1,250,000 U/mL

510(k) Summary, Continued

Feature	Elecsys CA 19-9	Fujirebio CA 19-9 RIA (predicate)
Limitations	The assay is unaffected by • icterus (bilirubin < 1129 µmol/L or < 66 mg/dL), • hemolysis (Hb < 1.4 mmol/L or < 2.2 g/dL), • lipemia (Intralipid < 1500 mg/dL), and • biotin < 100 ng/mL. • In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration. • No interference was observed from rheumatoid factors up to a concentration of 1500 IU/mL. • In vitro tests were performed on 27 commonly used pharmaceuticals. No interference with the assay was found. • As with all tests containing monoclonal mouse antibodies, erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies or have received them for diagnostic purposes. Elecsys CA 19-9 contains additives which minimize these effects. • In rare cases, interference due to extremely high titers of antibodies to streptavidin and ruthenium can occur.	• This assay should not be performed on clotted, icteric, hemolyzed or lipemic samples. • Human anti-mouse antibodies (HAMA) may be present in samples from patients who have received mouse monoclonal antibodies for immunotherapy. Such sample may show false elevated or depressed values when tested with this method. Results for patients suspected of having such antibodies should be carefully evaluated and interpreted in the context of the clinical status of the patient. • Can be used with serum and plasma prepared using different anti-coagulants (ACD-A, Citrate, EDTA, and Heparin). However, it is recommended that if the specimen type is changed during patient monitoring, the patient should be rebaselined to negate any potential biases due to specimen type. • Patients known to be genotypically negative for the Lewis blood group antigen will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis antigen may be produce varying levels of CA 19-9 based on gene dosage effect.

510(k) Summary, Continued

Feature	Elecsys CA 19-9	Fujirebio CA 19-9 RIA (predicate)
Limitations	• For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings. • Patients known to be genotypically negative for Lewis blood group antigens will be unable to produce the CA 19-9 antigen even in the presence of malignant tissue. Phenotyping for the presence of the Lewis blood group antigen may be insufficient to detect true Lewis antigen negative individuals. Even patients who are genotype positive for the Lewis antigen may produce varying levels of CA 19-9 as the result of gene dosage effect.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corp.
c/o Ms Kay A. Taylor
9115 Hague Rd.
Indianapolis, IN 46250

JUL 6 - 2005

Re: k050231
Trade/Device Name: Elecsys CA 19-9 Immunoassay
Elecsys CA 19-9 CalSet
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: NIG, JIT
Dated: January 21, 2005
Received: January 26, 2005

Dear Ms Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) -- premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050231

Device Name: Elecsys CA 19-9 Immunoassay
Elecsys CA 19-9 CalSet

Indications For Use:

IMMUNOASSAY

Immunoassay for the in vitro quantitative determination of CA 19-9 tumor associated antigen, in human serum and plasma.

The assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in the monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort.

*The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on the Roche Elecsys 1010/2010 and MODULAR ANALYTICS E170 (Elecsys module) immunoassay analyzers.*

CALSET

Elecsys CA 19-9 is used for calibrating the quantitative Elecsys CA 19-9 assay on the Elecsys immunoassay systems.

Prescription Use XXX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K050231